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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,616	06/10/2002	Roger N. Brummel	A0000060-01-DRK	7778

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EXAMINER	
KWON, BRIAN YONG S	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 02/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/018,616	BRUMMEL ET AL.	
	Examiner	Art Unit	
	Brian S. Kwon	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 June 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 4-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 4-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/1/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Summary of Action

1. The rejection of the claim 5 under 35 USC 112, first paragraph, is not maintained in light of the amendment.

2. The rejection of the claim 3 and 5under 35 USC 112, second paragraph, is not maintained in light of the amendment.

3. The rejection of the claim 5 under 35 USC 102(b) as being anticipated by Kompis et al. (US 5721242) is not maintained in light of the amendment.

4. The rejection of the claims 1-2, 6-7 and 9 under 35 USC 102(e) as being anticipated by Hurtt et al. (US 6451857 B1) is maintained for the reason of the record.

5. The rejection of the claims 4 and 8 under 35 USC 103(a) as being unpatentable over Hurtt et al. (US 6451857 B1) is maintained for the reason of the record.

Information Disclosure Statement

6. Acknowledgment is made of applicant's submitting of the information disclosure statement (IDS) on July 01, 2004.

With respect to US 5721242 and US 6451857 in the submitted PTO-1449, those references had been considered by the examiner (see the signed 1449 mailed on 12/22/03).

Status of Application

7. By Amendment filed 6/22/2004, claim 3 has been cancelled; claims 1, 4-7 have been amended; and claim 10 has been newly added. Claims 1, 2 and 4-10 are currently pending for the prosecution on the merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

8. Claims 1-2, 6-7 and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by Hurtt et al. (US 6,451,857 B1).

The claims 1-2 are drawn to a composition comprising gabapentin and pregabalin wherein claim 2 requires gabapentin and pregabalin "in the form of the free acid". The claims 6-7 and 9 are drawn to a method for the treatment of pain with said composition wherein claim 6 requires "unit dosage form"; claim 7 requires "concomitant administration" of gabapentin and pregabalin; and claim 9 requires "hyperalgesia, allodynia and inflammatory".

With respect to claims 1-2, 6 and 9,

Hurtt teaches a composition comprising two or more anti-epileptic compounds combined with one or more compounds selected from NSAID, analgesic, NMDA receptor antagonists, or

combinations thereof, namely gabapentin/pregabalin/opioid, gabapentin/pregabalin/NSAID, gabapentin/pregabalin/naproxen (column 5, lines 38-49), that is useful for treating pain including inflammatory pain (column 5, lines 50-60 and column 6, lines 8-19) wherein said composition is prepared in unit dosage form (column 6, lines 20-45).

Since the instant claims allow for the inclusion of any other unspecified ingredients in the composition by reciting open transitional language such as "comprises", the referenced composition anticipates the claimed invention.

Although Hurtt is silent about "said effective amounts have a synergistic effect", such characteristic or property is not limiting to the interpretation of the composition. Claims to a composition possessing a particular property or characteristic are still properly rejected by a reference to the same composition, even if the reference does not address or acknowledge the property. In the instance, the claimed "a synergistic effect" of said composition is deemed to be inherent to the combination composition. Thus, the referenced composition anticipates the claimed invention.

Although Hurtt is silent about the presence of gabapentin and pregabalin "in the form of the free acid", the referenced gabapentin and pregabalin in said composition must be inherently presented in the composition "in the form of the free acid" since the referenced gabapentin and pregabalin in Hurtt are used in the form of compound, not in salt forms. Therefore, the reference anticipates the claimed invention.

With respect to claim 7,

Hurtt also teaches the claimed method for treating pain by the co-administration of said composition (column 2, lines 41-52 and column 6, lines 1-7).

Since the referenced co-administration "metes and bounds" the claimed "concomitant administration", the reference anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 4, 5, 8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hurtt et al (US 6,451,857 B1).

The teaching of Hurtt'857 has been discussed in above 35 USC 102(e) rejection.

The teaching of Hurtt'857 differs from the claimed invention in the specific range of ratio of gabapentin to pregarbalin or the specific range of dosage amount of gabapentin and pregabalin in the composition wherein the claims require the ratio of gabapentin to pregabalin " from 1:1 to 1000:1" by weight (claim 4), "the ratio of gabapentin to pregabalin from 1:1 to 250:1 by weight" (claim 5), "gabapentin is administered in the amount of from 5 to 250mg and pregabalin in the amount of from 5 to 25mg" (claim 8), and "the ratio of gabapentin to pregabalin is from 1:1 to 10:1 by weight". However, the determination of a dosage or ratio having the optimum therapeutic is well within the skill of one having ordinary skill in the art, and the artisan would be motivated to determine optimum amounts to get the maximum effect of the drug. Those of ordinary skill in the art will readily optimize effective dosages or ratios as determined by good medical practice and the clinical condition of the individual patient. Regardless of the manner of administration, the specific dose may be calculated according to body weight, body surface area or organ size. Further refinement of the calculations necessary to determine the appropriate dosage for treatment involving each of the above mentioned formulations is routinely made by those of ordinary skill in the art and is within the ability of tasks routinely performed by them without undue experimentation.

Response to Arguments

10. Applicant's arguments filed June 22, 2004 have been fully considered but they are not persuasive.

In response to the rejection of the claims 3, 4 and 8 under 35 USC 102(e), applicants' argument takes position that Hurtt et al. do not teach each and every limitation required in the instant claims, especially characteristic of "synergistic effect" of said composition.

This argument is not persuasive at all. Claims to a composition possessing a particular property or characteristic are still properly rejected by a reference to the same composition, even if the reference does not address or acknowledge the property. Especially in view of effective dosage amount of the referenced antiepileptic compounds (i.e., gabapentin and pregabalin) having "pain relieving properties" (see column 1, lines 32-34; column 4, lines 1-6 of US'857), the examiner considers that both of the referenced composition and the instant composition are drawn to the same composition.

In response to the rejection of the claims 3, 4 and 8 under 35 USC 103(a), applicants' argument takes position that the reference does not teach or suggest the limitation of synergistic effect. Applicants state "Nor does Hurtt et al. contain any suggestion or incentive that would have motivated the skilled artisan to modify the combinations referred to in Hurtt et al. to arrive at the claimed compositions with the limitation of synergistic effect therein; let alone with a reasonable expectation of success".

This argument is not persuasive at all. With respect to the alleged "synergistic effect" of said composition, the examiner has discussed above, and believes that there is no need to discuss any further on this issue. The examiner maintains that the determination of dosage amounts or ratios having the optimum therapeutic index is considered within the skill of one having ordinary

skill in the art, and the artisan would be motivated to determine optimum amounts to get the maximum effect of the drug, especially in light of dosage information, "pain relieving properties" of gabepentin and pregabalin (column 1, lines 32-34; column 4, lines 1-6; column 5, lines 50-67; Example and claims of US'857).

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. No Claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (571) 272-0951. The fax number for this Group is (703) 872-9306.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Brian Kwon
Patent Examiner
AU 1614

VICKIE KIM
PRIMARY EXAMINER